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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
PORTNER, VIRGINIA ALLEN	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 08/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/764,212	SIMALA-GRANT ET AL.	
	Examiner	Art Unit	
	Ginny Portner	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 6/6/06.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-44 is/are pending in the application.

4a) Of the above claim(s) 1-23 and 28-44 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 24-27 is/are rejected.

7)☒ Claim(s) 24-27 is/are objected to.

8)☒ Claim(s) 1-44 are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 1/05;2/06.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-44 are pending.

SEQUENCE COMPLIANCE

1. Applicant's amendment has placed the instant Application in sequence compliance.

Election/Restrictions

2. Claims of Groups I and II, non-elected, and claims 28-30 of Group III, non-elected species are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Groups and species of invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on June 6, 2006.

3. Applicant's election with traverse of Group III, claims 23-30, SEQ ID NO 16 in the reply filed on June 6, 2006 is acknowledged. The traversal is on the ground(s) that three Groups of inventions set forth by the examiner would not constitute a serious burden to search. These arguments have been fully considered but are not found to be persuasive for the reasons below.

First, the classification system has no statutory recognition whether inventions are independent and distinct. For example, each class and subclass is comprised of numerous completely independent and distinct inventions.

Second, MPEP 803 states that restriction is proper between patentably distinct inventions where the inventions are (1) independent or distinct as claimed and (2) a serious search and examination burden is placed on the examiner if restriction is not required.

The term distinct is defined to mean that two or more subjects as disclosed are related, for example, as product and method of use, but are capable of separate manufacture, use or sale as claimed, and are patentable over each other (see MPEP 802.1). In the instant situation, the inventions of Groups I-, II and III are drawn to distinct inventions which are related as separate products capable of separate functions. A polynucleotide does not function in the same biological manner as a protein, nor would a polynucleotide add a fucose to a protein or substrate to produce a fucosylated product. Restrictions between the inventions is deemed to be proper for the reason previously set forth.

In regard to burden of search and examination, MPEP 803 states that a burden can be shown if the examiner shows either separate classification, different field of search or separate status in the art. Post-translational modification of substrates clearly is different, classified separately and is a different field of search from polynucleotides that encode a protein product that which may be used in a method of detection of a bacterial pathogen that produces a fucosyltransferase. In the instant case a burden has been established in showing that the inventions of Groups I-III are classified separately necessitating different searches of issued US Patents (435/69.1; 536/23.7 and 530/350). However, classification of subject matter is merely one indication of the burdensome nature of search. The literature search, particularly relevant in this art, is not co-extensive, because for example a search of a polynucleotide sequence would not identify a fucosylated product production method. Additionally, it is submitted that the inventions of Groups have acquired a separate status in the art. Clearly different searches and issues are involved in the examination of each Group.

For these reasons the restriction requirement is deemed to be proper and is therefore made Final.

Ochiai/Brouwer Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP э 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined

claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See AGuidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. ə 103(b),≅ 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP ə 804.01. The requirement is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

1. The information disclosure statement filed January 31, 2005 and February 17, 2006 have been considered.

Specification

2. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. The hyperlink on page 19, line 17 should be removed.

Claim Objections

3. Claims 24-27 are objected to because of the following informalities:

a. Claims 24-27 recite non-elected inventions; cancellation of the non-elected invention would clearly set forth Applicant's elected invention.

b. Claims 24-27 are missing a transitional phrase "a polypeptide has greater " should read------a polypeptide that has greater--------.

c. Appropriate correction is required.

Please Note:

- The following prior art rejections are being made of record in light of the definitions provided by the instant Specification at [0045-0047] which defines a genus of functionally defined fucosyltransferase proteins which evidence amino acid sequences that may only comprise a conserved region (see Spec. p.9, line 6) with a reference sequence or evidence a common function ("polymorphic variants, alleles, mutants, interspecies homologs" relative to a sequence identifier).

- Additionally, the phrase "A recombinant fucosyltransferase protein is being read as product by process language that permits the claimed protein of SEQ ID NO 16 to be made by another process.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who

has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

5. Claims 24-25, and 27 are rejected under 35 U.S.C. 102(e) as being anticipated by Taylor and Ge (US Pat. 6,962,806, filing date July 3, 2002)

The applied reference has a common Taylor, Diane with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Instant claim 24: Taylor et al discloses and claims the instant invention that is directed to a fucosyltransferase that comprises an amino acid sequence with at least 90% identity with SEQ Id NO 16, the amino acid sequence of Taylor et al that shares this degree of identity is "DDLRVNY" located at the C-terminal end of SEQ ID NO 16, amino acid residue positions near 373-379 (see Taylor et al, claims 1-4).

Instant claim 25: further comprises an amino acid tag " (see Taylor et al, claim 8, "fusion protein", claim 9, "an IgFc fusion protein", claim 11 "a fluorescent protein or a luminescent protein").

Instant claim 27: wherein the fucosyltransferase catalyzes the transfers a Fucose to an acceptor molecule that is N-acetylglucosamine residue (see Taylor et al, claim 5). Taylor et al anticipates the instantly claimed invention as now claimed.

6. Claims 24 and 27 are rejected under 35 U.S.C. 102(b or e) as being anticipated by Taylor and Ge (PG-Pub 2002/0164749, publication date November 7, 2002)

The applied reference has a common Taylor, Diane with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Instant claim 24: Taylor et al discloses and claims the instant invention that is directed to a fucosyltransferase that comprises an amino acid sequence with at least 90% identity with SEQ Id NO 16, the amino acid sequence of Taylor et al that shares this degree of identity is defined by a formula (see Taylor et al, claim 9) which encompasses the amino acid sequence"DDLRVNY" located at the C-terminal end of SEQ ID NO 16, amino acid residue positions near 373-379 (see Taylor et al, claims 1-2 and 9).

Instant claim 27: wherein the fucosyltransferase catalyzes the transfers a Fucose to an acceptor molecule that is N-acetylglucosamine residue (see Taylor et al, claim 2). Taylor et al anticipates the instantly claimed invention as now claimed.

7. Claims 24, 25 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Wang et al (2000).

Wang et al disclose the instantly claimed invention directed to a fucosyltransferase protein of Helicobacter pylori, to include Helicobacter pylori strain UA111 and strains 0651 and 596 (see futB, Table 1; and Figure 1, last couple lines of table B "UA1111" and Fig. 2, page 1190, top of col. 1, frame C), that comprises an amino acid sequence selected from SEQ ID NO 16 (see sequence alignments for strains 0651 and 596 attached herewith) and for strain UA1111, the fucosyltransferase inherently comprises the SEQ ID NO 16, as the fucosyltransferase that has the amino acid sequence represented by SEQ ID NO 16 was isolated from H.pylori strain UA 1111, wherein the fucosyltransferase of strain UA1111 was isolated and activity measured (see page 192, col. 1, bottom of paragraph 2 "UA111 contains an α 1,2 FucT and an α 1,3/4 FucT that have a comparable level of activity, resulting in the predominant Le^b". The fucosyltransferases of Wang et al having been defined to transfer a fucose from an acceptor molecule that is an N-acetylglucosamine (see Figure 1, Frames A and B, for Lewis A and B antigens for various Helicobacter strains, to include strain UA111.

Wang et al anticipates the instant claimed invention as now claimed, in light of the fact that the fucosyltransferase is not so claimed to evidence any biological characteristics that would not be present in same fucosyltransferase isolated from Helicobacter pylori.

8. Claims 24, 25 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Rasko et al (2000).

Rasko et al disclose the instantly claimed invention directed to a fucosyltransferase protein of Helicobacter pylori (see title), that comprises an amino acid sequence selected from SEQ ID NO 16 (see Table 1, conserved repeat sequences of fucosyltransferases (page 4990)) and therefore comprises an amino acid sequence of the polypeptide represented by SEQ ID NO 16, and the fucosyltransferase was expressed recombinantly (see page 4992, Table II, "heterologously expressed") and evidenced fucosyltransferase activity based upon the Lewis antigens produced (see Table II, and Figure 1, page 4989, top of page that shows the functional biological activity of fucosyltransferases. The fucosyltransferases of Rasko et al having been defined to transfer a fucose from an acceptor molecule that is an N-acetylglucosamine (see Figure 1,page 4989). Rasko et al anticipates the instantly claimed invention as now claimed, in light of the fact that Rasko et al disclose a recombinant H.pylori fucosyltransferase that comprises an amino acid sequence of SEQ ID NO 16 (see Table 1, page 4990). Rasko anticipates the instantly claimed invention as now claimed.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 24, 25, 27 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No.6,962,806. Although the conflicting claims are not identical, they are not patentably distinct from each other because Taylor et al discloses and claims the instant invention that is directed to a fucosyltransferase that comprises an amino acid sequence with at least 90% identity with SEQ Id NO 16, the amino acid sequence of Taylor et al that shares this degree of identity is "DDLRVNY" located at the C-terminal end of SEQ ID NO 16, amino acid residue positions near 373-379 (see Taylor et al, claims 1-4). **Instant claim 25**: further comprises an amino acid tag " (see Taylor et al, claim 8, "fusion protein", claim 9, "an IgFc fusion protein", claim 11 "a fluorescent protein or a luminescent protein"). **Instant claim 27**: wherein the fucosyltransferase catalyzes the transfers a Fucose to an acceptor molecule that is N-acetylglucosamine residue (see Taylor et al, claim 5). Taylor et al anticipates the instantly claimed invention as now claimed. The allowed species of invention anticipates the instantly claimed genus of fucosyltransferases. While the allowed claims do not recite the term "recombinant", allowed claim 8 defines the allowed fucosyltransferases to be a "fusion protein" (allowed claim 8), which is a species of recombinant fucosyltransferase protein with an amino acid tag. The allowed claims of Taylor et al obviates the instantly claimed genus directed to fucosyltransferase proteins now claimed.

11. Claims 24 and 27 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2 and 9 of copending Application No. (Taylor and Ge, PG-Pub 2002/0068347, publication date June 6, 2002). Although the conflicting claims are not identical, they are not patentably distinct from each other because Taylor et al discloses and claims the instant invention that is directed to a fucosyltransferase that comprises an amino acid sequence with at least 90% identity with SEQ Id NO 16, the amino acid sequence of Taylor et al that shares this degree of identity is defined by a formula (see Taylor et al, claim 9) which encompasses the amino acid sequence"DDLRVNY" located at the C-terminal end of SEQ ID NO 16, amino acid residue positions near 373-379 (see Taylor et al, claims 1-2 and 9), wherein the fucosyltransferase catalyzes the transfers a Fucose to an acceptor molecule that is N-acetylglucosamine residue (see Taylor et al, claim 2). The allowed species of Taylor et al anticipates the instantly claimed genus of fucosyltransferase proteins.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

12. Claims 24 and 27 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2 and 9 of copending Application No. (Taylor and Ge, PG-Pub 2002/0164749, publication date November 7, 2002). Although the conflicting claims are not identical, they are not patentably distinct from each other because Taylor et al discloses and claims the instant invention that is directed to a fucosyltransferase that comprises an amino acid sequence with at least 90% identity with SEQ Id NO 16, the amino acid sequence of Taylor et al that shares this degree of identity is defined by a formula (see Taylor et

al, claim 9) which encompasses the amino acid sequence"DDLRVNY" located at the C-terminal end of SEQ ID NO 16, amino acid residue positions near 373-379 (see Taylor et al, claims 1-2 and 9), wherein the fucosyltransferase catalyzes the transfers a Fucose to an acceptor molecule that is N-acetylglucosamine residue (see Taylor et al, claim 2). The allowed species of Taylor et al anticipates the instantly claimed genus of fucosyltransferase proteins.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on flextime, but usually M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vgp August 14, 2006

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